FDA 510(k) Premarket Notification

K221489 Artemis Proximal Femoral Nail System

CLEARED

Oct 27, 2022
157 days to decision

K221489 · Product code: **HSB** · Orthopedic
Source: https://www.510kdatabase.net/k221489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	May 23, 2022
Decision date	Oct 27, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Glw, Inc.**
Location	Englewood Cliff, NJ, US
Contact	Arundhati Radhakrishnan
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Wagoner Consulting, LLC**
Contact	Cheryl Wagoner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov